



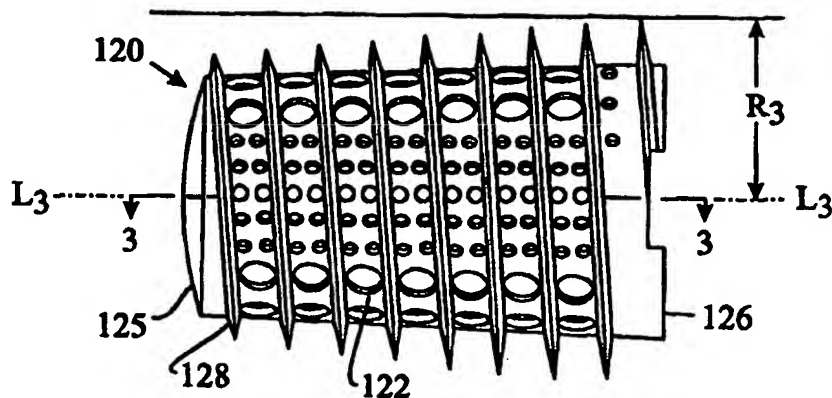
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 5/04	A1	(11) International Publication Number: WO 96/40020 (43) International Publication Date: 19 December 1996 (19.12.96)
(21) International Application Number: PCT/US96/08618 (22) International Filing Date: 6 June 1996 (06.06.96) (30) Priority Data: 08/480,908 7 June 1995 (07.06.95) US (71)(72) Applicant and Inventor: MICHELSON, Gary, K. [US/US]; 438 Sherman Canal, Venice, CA 90291 (US). (74) Agent: SCHELLIN, Eric, P.; Suite 704, 2121 Crystal Drive, Arlington, VA 22202 (US).	(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

(54) Title: THREADED FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS

(57) Abstract

The present invention is directed to a variety of interbody spinal fusion implants (20) having at least a partially frusto-conical configuration. An external thread (28) is employed to increase implant stability and implant surface area, and for the purpose of advancing the spinal fusion implant (20) into the fusion site. The spinal fusion implants (20) of the present invention may be relatively solid or hollow and may have surface roughening to promote bone ingrowth and stability. The spinal fusion implants (20) of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

**THREADED FRUSTO-CONICAL INTERBODY
SPINAL FUSION IMPLANTS**

BACKGROUND OF THE INVENTION

Related Applications

5 This application is a continuation in part of
copen ding United States application Serial No. 08/396,414
filed on February 27, 1995 which is a continuation-in-part
of United States application Serial No. 08/074,781 filed on
June 10, 1993, which is a continuation in part of United
10 States application Serial No. 07/698,674 filed on May 10,
1991 which is a divisional of application Serial No.
07/205,935 filed on June 13, 1988, now United States Patent
No. 5,015,247, all of which are incorporated herein by
reference.

15 This application is also a continuation-in-part
of United States application Serial No. 08/390,131 entitled
Interbody Spinal Fusion Implants filed on February 17,
1995.

Field of the Invention

20 The present invention relates generally to
interbody spinal fusion implants, and in particular to
spinal fusion implants configured to restore and maintain
two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

25 Interbody spinal fusion refers to the method of
achieving bony bridging between adjacent vertebrae through
the disc space, the space between adjacent vertebrae
normally occupied by a spinal disc. Numerous implants to
facilitate such a fusion have been described by Cloward,
30 Brantigan, and others, and are known to those skilled in
the art. Generally, cylindrical implants offer the

advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Therefore, there exists a need for spinal fusion implants that permit for the restoration of anatomical lordosis.

SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration. In the preferred embodiment, the spinal fusion implants of the present invention have a body that is partially or fully frusto-conical shape substantially along the portion of the implant in contact with the adjacent vertebrae of the spine. The spinal fusion implants of the present invention have an external thread for engaging the adjacent vertebrae of the spine and have an insertion end and a trailing end. The external thread may have a variable or constant thread radius and/or a constant or variable thread height measured from the body of the implant.

The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a frusto-cone, at least one side portion may be truncated to form a planar surface that is parallel to the central longitudinal axis of the

implant to form straight walls. These implants may have a more tapered aspect at the insertion end of the implant to facilitate insertion. The spinal fusion implants of the present invention may be relatively solid and/or porous and/or hollow, and may have surface roughenings to promote bone ingrowth and stability.

The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. These wells, or holes, may pass either into or through the implant and may or may not intersect. The spinal fusion implants of the present invention may have at least one chamber which may be in communication through at least one opening to the surface of the implant.

Said chamber may have at least one access opening for loading the chamber with fusion promoting substances. The access opening may be capable of being closed with a cap or similar means.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially frusto-conical in shape, those that taper from the leading edge to the trailing edge are easy to introduce and easy to fully insert into the spinal segment to be fused. In another embodiment, where the trailing edge of the implant is larger than the leading edge, the implant utilizes a tapered forward portion and an increasing thread height relative to the body from the leading

edge to the trailing edge to facilitate insertion.

2. The shape of the implants of the present invention is consistent with the shape of the disc, which the implants at least in part replace, wherein the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.

3. The spinal fusion implants of the present invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics or combination sufficient for the intended purpose. Further, the spinal fusion implants of the present invention may be made of a solid material, a mesh-like material, a porous material and may comprise, wholly or in part, materials capable of directly participating in the spinal fusion process, or be loaded with, composed of, treated or coated with chemical substances such as bone, morphogenic proteins, hydroxyapatite in any of its forms, and osteogenic proteins, to make them bioactive for the purpose of stimulating spinal fusion. The implants of the present invention may be wholly or in part bioabsorbable.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fusion implant that is easily inserted into the spine, having a tapered leading end;

5 It is another object of the present invention to provide a spinal fusion implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

10 It is yet another object of the present invention to provide a spinal fusion implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

15 It is still another object of the present invention to provide a spinal fusion implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of providing stability between adjacent vertebrae when inserted;

20 It is still another object of the present invention to provide a spinal fusion implant that is capable of participating in the fusion process by containing, being composed of, or being treated with fusion promoting substances;

25 It is further another object of the present invention to provide a spinal fusion implant that is capable of spacing apart and supporting adjacent vertebrae during the spinal fusion process;

30 It is still further another object of the present invention to provide a spinal fusion implant that is consistent in use with the preservation of a uniform

thickness of the subchondral vertebral bone;

It is another object of the present invention to provide a spinal fusion implant having a shape which conforms to an easily produced complementary bore at the fusion site; and

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual heights of each implant.

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual lengths of each implant.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the spinal fusion implant of the present invention having a body that is frusto-conical with an external thread having a substantially uniform radius.

Figure 1A is an enlarged fragmentary view along line 1A of Figure 1 illustrating the surface configuration of the implant of Figure 1.

Figure 1B is an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present

invention made of a cancellous material.

Figure 1C is a cross sectional view along lines 1C--1C of Figure 1B illustrating the alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

Figure 1D is an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material.

Figure 1E is a fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention comprising a plurality of spaced apart posts.

Figure 1F is an enlarged fragmentary sectional view along lines 1F--1F of Figure 1E illustrating the surface configuration of the implant of Figure 1E.

Figure 2 is an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body with an external thread radius and thread height that are not constant.

Figure 3 is a cross sectional view along line 3--3 of the implant of Figure 2.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention.

Figure 5 is a side elevational view and partial cut-away of a segment of the spinal column in lordosis showing the spinal fusion implant of Figure 4 being implanted with a driving instrument from the posterior approach to the spinal column.

Figure 6 is a side elevational view of an

alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body and truncated sides.

5 Figure 7 is an end view along line 7--7 of the spinal fusion implant of Figure 6 shown placed beside a second identical implant shown in hidden line.

Figure 8 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body with an irregular
10 configuration.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figure 1, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral 20 is shown. The implant
15 20 has a body 22 that is frusto-conical in shape such that the body 22 has a diameter (root diameter) that is generally frusto-conical. The body 22 has an insertion end 24 and a trailing end 26. The insertion end 24 may include a tapered portion 25 to facilitate insertion of the spinal
20 implant 20. In the preferred embodiment, when the implant 20 is inserted from the anterior aspect of the spine, the body 22 of the implant 20 has a maximum diameter at a point nearest to the trailing end 26 and a minimum diameter at a point nearest to the insertion end 24.

25 The implant 20 has an external thread 28 having a substantially uniform radius R_1 measured from the central longitudinal axis L_1 of the implant 20. The outer locus of the external thread 28 (major diameter) has an overall configuration that is substantially parallel to the
30 longitudinal axis L_1 . While the major diameter of the implant 20 is substantially uniform, the external thread 28

may be modified at the leading edge by having initially a reduced thread radius to facilitate insertion of the implant 20 and may also be modified to make the external thread 28 self-tapping. In the preferred embodiment, the external thread 28 has a first thread 30 of a lesser radius than the radius R_1 of the remainder of the external thread 28 to facilitate insertion of the implant 20. The second thread 32 has a greater radius than the first thread 30, but is still shorter than the radius R_1 of the remainder of the external thread 28 which is thereafter of constant radius.

The body 22 is frusto-conical substantially along the portion of the body 22 in contact with the adjacent vertebrae of the spine which allows for creating and maintaining the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The substantially uniform radius R_1 of the external thread 28 of the implant 20 allows engaging the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant 20 from between the adjacent vertebrae in the direction opposite to which the implant 20 was implanted. The greater thread height measured from the body 22 near the leading end 24 of the implant 20 provides greater purchase into the vertebral bone and again enhances the stability of the implant 20. Further, the configuration of the external thread 28 increases the surface area of the implant 20 in contact with the vertebrae to promote bone ingrowth.

The implant 20 has a recessed slot 34 at its trailing end 26 for receiving and engaging insertion

instrumentation for inserting the implant 20. The recessed slot 34 has a threaded opening 36 for threadably attaching the implant 20 to instrumentation used for inserting the implant 20.

5 Referring to Figure 1A, the implant 20 has an outer surface 38 that is porous to present an irregular surface to the bone to promote bone ingrowth. The outer surface 38 is also able to hold fusion promoting materials and provides for an increased surface area to engage the
10 bone in the fusion process and to provide further stability. The pores of the outer surfaces 38 are microscopic in size having a diameter that is less than 1mm, in the range of 50-1000 microns, with 250-500 microns being the preferred diameter. It is appreciated that the
15 outer surface 38, and/or the entire implant 20, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant 20 may be further coated with
20 bioactive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins. The implant 20 is shown as being solid, however it is appreciated that it can be made to be substantially hollow or hollow in part.

25 Referring to Figure 1B, an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration 38 of the implant of the present invention made of a cancellous material is shown. The cancellous material 50, similar in
30 configuration to human cancellous bone, having interstices 52 such that the outer surface 38 has a configuration as

shown in Figures 1B and 1C. As the implant of the present invention may be made entirely or in part of the cancellous material 50, the interstices 52 may be present in the outer surface 338 and/or within the entire implant to promote bone ingrowth and hold bone fusion promoting materials.

Referring to Figure 1D, an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material is shown. The mesh-like material 60 comprises strands 62 that are formed and pressed together such that interstices 64, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface 38 of implant of the present invention.

Referring to Figures 1E and 1F, a fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration 38 of the implant of the present invention comprising a plurality of spaced apart posts 70 is shown. The posts 70 have a head portion 72 of a larger diameter than the remainder of the posts 70, and each of the interstices 74 is the reverse configuration of the posts 72, having a bottom 76 that is wider than the entrance to the interstices 74. Such a configuration of the posts 70 and interstices 74 aids in the retention of bone material in the surface 38 of the implant and further assists in the locking of the implant into the bone fusion mass created from the bone ingrowth. As the bone ingrowth at the bottom 76 of the interstices is wider than the entrance, the bone ingrowth cannot exit from the entrance and is locked within the interstice 74. The surface of the

implant provides for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

5 In the preferred embodiment, the posts 70 have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of approximately 0.1-2 mm such that the interstices 74 have a width in the range of approximately
10 0.1 to 2 mm. The post sizes, shapes, and distributions may be varied within the same implant.

 In the preferred embodiment, for use in the
15 lumbar spine, the implant 20 has an overall length in the range of approximately 24 mm to 32 mm with 26 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-20 mm, with 14-16 mm being the preferred root diameter at the
20 insertion end, and a root diameter at the trailing end 26 in the range of 10-24 mm, with 16-18 mm being the preferred diameter at the trailing end 26, when said implants are used in pairs. When used singly in the lumbar spine, the preferred diameters would be larger.

25 In the preferred embodiment, the implant 20 has a thread radius R_1 in the range of 6 mm to 12 mm, with 9-10 mm being the preferred radius R_1 . For use in the cervical spine, the implant 20 has an overall length in the range of approximately 10-22 mm, with 12-14 mm being the preferred
30 length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-22 mm, with 16-18

mm being the preferred root diameter at the insertion end when used singly, and 8-10 mm when used in pairs. The body 22 of the implant 20 has a root diameter at the trailing end 26 in the range of 10-24 mm, with 18-20 mm
5 being the preferred root diameter at the trailing end 26 when used singly, and 10-12 mm when used in pairs; a thread radius R_1 in the range of approximately 4-12 mm, with 9-10 mm being the preferred radius R_1 when inserted singularly and 5-7 mm when inserted side by side in pairs.

10 Referring to Figure 2, an alternative embodiment of implant 20 is shown and generally referred to by the numeral 120. The implant 120 has a body 122 similar to body 122 of implant 120 and has an external thread 128 having a radius R_3 measured from the central longitudinal
15 axis L_3 of the implant 120. The thread radius R_3 is not constant throughout the length of the implant 120 and the external thread 128 has a thread height that is also not constant with respect to the body 122 of the implant 120. In the preferred embodiment, the implant 120 has an
20 external thread 128 with a radius R_3 that increases in size from the insertion end 124 to the trailing end 126 of the implant 120.

Referring to Figure 3, a cross sectional view along line 3--3 of the implant 120 is shown. The implant
25 120 has an outer wall 144 surrounding an internal chamber 146. The large and small openings 140 and 142 may pass through the outer wall 144 to communicate with the internal chamber 146. The internal chamber 146 may be filled with bone material or any natural or artificial bone growth
30 material or fusion promoting material such that bone growth occurs from the vertebrae through the openings 140 and 142

to the material within internal chamber 146. While the openings 140 and 142 have been shown in the drawings as being circular, it is appreciated that the openings 140 and 142 may have any shape, size configuration or distribution, suitable for use in a spinal fusion implant without departing from the scope of the present invention.

The openings 140 and 142 are macroscopic in size having a diameter that is greater than 1 mm. The large openings 140 have a diameter in the range of 206 mm, with the preferred diameter being 3.5mm; and the small openings have a diameter in the range of 1-2 mm, with 1.5 mm being the preferred diameter.

The implant 120 has a cap 148 with a thread 150 that threadably attaches to the insertion end 124 of the spinal fusion implant 120. The cap 148 is removable to provide access to the internal chamber 146, such that the internal chamber 146 can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap 148 and/or the spinal fusion implant 120 may be made of any material appropriate for human implantation including metals such as cobalt chrome, stainless steel, titanium, plastics, ceramics, composites and/or may be made of, and/or filled, and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. The cap

148 and the implant 120 may be partially or wholly bioabsorbable.

Referring to Figure 4, a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention generally referred to by numeral 520 is shown. The implant 520 has a body 522 having a root diameter that is frusto-conical in the reverse direction as that of implant 20 shown in Figure 1, in order to preserve and/or restore lordosis in a segment of spinal column when inserted from the posterior aspect of the spine. The body 522 has an insertion end 524 and a trailing end 526. In the preferred embodiment, the body 522 of the implant 520 has a minimum diameter at a point nearest to the trailing end 526 and a maximum diameter at a point nearest to the insertion end 524. The insertion end 524 may have an anterior nose cone portion 530 presenting a tapered end to facilitate insertion.

The implant 520 has an external thread 528 having a substantially uniform radius R_6 measured from the central longitudinal axis L_6 of the implant 520, such that the external diameter of the external thread 528 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_6 . It is appreciated that the thread 528 can have a major diameter that varies with respect to the longitudinal axis L_6 , such that the major diameter may increase from the insertion end 524 to the trailing end 526 or the reverse. The external thread 528 has a thread height measured from the body 522 that increases from the insertion end 524 to the trailing end 526.

Referring to Figure 5, a segment of the spinal

column S is shown with the vertebrae V_1 and V_2 in lordosis and an implant 520 shown being inserted from the posterior aspect of the spinal column S with an instrument driver D. The implant 520 is inserted with the larger diameter insertion end 524 first in order to initially distract apart the vertebrae V_1 and V_2 which then angle toward each other posteriorly as the implant 520 is fully inserted. It is appreciated that the insertion of implant 520 does not require the adjacent vertebrae V_1 and V_2 to be placed in lordosis prior to insertion, as the full insertion of the implant 520 itself is capable of creating the desired lordotic angular relationship of the two vertebrae V_1 and V_2 .

In the preferred embodiment, for use in the lumbar spine, the implant 520 has an overall length in the range of approximately 24 mm to 30 mm, with 26 mm being the preferred length. The body 522 of the implant 520 has a root diameter at the insertion end 524 in the range of 12-22 mm, with 16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 526 in the range of 10-20 mm, with 14 mm being the preferred diameter at the trailing end 526. In the preferred embodiment, the implant 520 has a thread radius R_6 in the range of 6 mm to 12 mm, with 8 mm being the preferred radius R_6 .

Referring to Figure 6, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral 620 and a partial fragmentary view of a second identical implant, generally referred to by the numeral 621 are shown. The implant 620 has a body 622 that is partially frusto-conical in shape

similar to body 22 of implant 20 shown in Figure 1, and has an insertion end 624 and a trailing end 626. The body 622 of the implant 620 has truncated sides 670 and 672 forming planar surfaces that are parallel to the longitudinal axis L_7 . In this manner, two implants 620 and 621 may be placed side by side, with one of the sides 670 or 672 of each implant with little space between them, such that the area of contact with the bone of the adjacent vertebrae is maximized. It is appreciated that the body 622 may also be cylindrical in shape and have truncated sides 670 and 672.

The implant 620 has an external thread 628 having a radius R_6 measured from the central longitudinal axis L_7 that may be constant, such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially cylindrical. It is appreciated that the external thread 628 may have a thread radius R_7 that is variable with respect to the longitudinal axis L_7 such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially frusto-conical.

Referring to Figure 7, an end view of the implant 620 placed beside implant 621 is shown. The implant 620 has a thread radius that is substantially constant and has a thread height measured from the body 622 that is greater at the sides 670 and 672. In this manner, two implants 620 and 621 can be placed beside each other with the external thread 628 of each implant interdigitated allowing for closer adjacent placement of the two implants as a result of the substantial overlap of the external thread 628 at

the side 670 or 672 of the implants.

Referring to Figure 8, an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 700. The implant 700 is similar in configuration to implant 20 shown in Figure 1, except that the body 722 has an irregular configuration. The configuration of the body 722 has a root diameter D which is variable in size throughout the length of the implant 700 and, as shown in this embodiment, comprises larger diameter portions 750 and smaller diameter portions 752. It is appreciated that each of the large diameter portions 750 may be of the same or different diameter and each of the smaller diameter portions 752 may be of the same or different diameter.

The outer surface of the body 722 of implant 720 may be filled with fusion promoting substances such that the smaller diameter portions 752 may hold such fusion promoting substances. If so filled, the composite of the implant 700 and the fusion promoting material could still produce an even external surface of the body 722 if so desired.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

Each of the features disclosed in the various

embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.

What is claimed is:

1. A frusto-conical interbody spinal fusion implant, comprising:

5 a body having an insertion end, a trailing end and an outer surface; and

an external thread for engaging said implant to adjacent vertebrae of the spine, the outer locus of said external thread forming a substantially frusto-conical configuration, said implant being made of a material
10 appropriate for human implantation.

2. The implant of claim 1 in which said body has a substantially frusto-conical configuration.

3. The implant of claim 1 in which said body has a substantially cylindrical configuration.

15 4. The spinal fusion implant of claim 1 in which said trailing end is larger than said insertion end.

5. The spinal fusion implant of claim 1 in which said insertion end is larger than said trailing end.

20 6. The spinal fusion implant of claim 1 in which said implant comprises a bone ingrowth material.

7. The spinal fusion implant of claim 1 in which said implant comprises a fusion promoting material.

8. The spinal fusion implant of claim 1 in which said implant is at least in part bioabsorbable.

25 9. The spinal fusion implant of claim 1 having a plurality of openings capable retaining fusion promoting material.

30 11. The spinal fusion implant of claim 1 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform throughout at least a

portion of said implant.

12. The spinal fusion implant of claim 1 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread
5 radius being variable along the length of said implant.

13. The spinal fusion implant of claim 1 in which said external thread has a thread height measured from said body which is variable along the length of said implant.

14. The spinal fusion implant of claim 1 in which
10 said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

15. The spinal fusion implant of claim 1 in which said outer surface is porous at least in part.

16. The spinal fusion implant of claim 1 in which
15 said implant has an internal chamber and an access opening for accessing said internal chamber.

17. The spinal fusion implant of claim 16 in which said internal chamber is capable of containing fusion
20 promoting material.

18. The spinal fusion implant of claim 16 in which said implant comprises a wall surrounding said internal chamber.

19. The spinal fusion implant of claim 16 in which
25 said wall has a plurality of openings passing therethrough in communication with said internal chamber.

20. The spinal fusion implant of claim 16 in which said implant has means for closing said access opening.

21. The spinal fusion implant of claim 1 in which
30 said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

22. The spinal fusion implant of claim 1 in which at least a portion of said outer surface comprises wells having at least partial walls.

23. The spinal fusion implant of claim 1 in which
5 said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said
10 first and second implants.

24. The spinal fusion implant of claim 1 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

25. The spinal fusion implant of claim 24 in which
15 said external thread has a thread height measured from said body which is greatest at said truncated side.

26. A frusto-conical interbody spinal fusion implant, comprising:

a body having an insertion end, a trailing end and an
20 outer surface; and

an external thread for engaging said implant to adjacent vertebrae of the spine, the locus of said external thread forming a substantially cylindrical configuration, said implant being made of a material appropriate for human
25 implantation.

27. The implant of claim 26 in which said body has a substantially frusto-conical configuration.

28. The implant of claim 26 in which said body has at least in part a cylindrical configuration.

29. The spinal fusion implant of claim 26 in which
30 said trailing end is larger than said insertion end.

30. The spinal fusion implant of claim 26 in which said insertion end is larger than said trailing end.

31. The spinal fusion implant of claim 26 in which said implant comprises a bone ingrowth material.

5 32. The spinal fusion implant of claim 26 in which said implant comprises a fusion promoting material.

33. The spinal fusion implant of claim 26 in which said implant is at least in part bioabsorbable.

10 34. The spinal fusion implant of claim 26 having a plurality of openings capable retaining fusion promoting material.

35. The spinal fusion implant of claim 26 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread
15 radius being substantially uniform throughout the length of said implant.

36. The spinal fusion implant of claim 26 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread
20 radius being variable along at least a portion of said implant.

37. The spinal fusion implant of claim 26 in which said external thread has a thread height measured from said body which is variable along the length of said implant.

25 38. The spinal fusion implant of claim 26 in which said external thread has a thread height measured from said body which is substantially constant along at least a portion of said implant.

39. The spinal fusion implant of claim 26 in which
30 said outer surface is porous at least in part.

40. The spinal fusion implant of claim 26 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

5 41. The spinal fusion implant of claim 26 in which said internal chamber is capable of containing fusion promoting material.

42. The spinal fusion implant of claim 40 in which said implant comprises a wall surrounding said internal chamber.

10 43. The spinal fusion implant of claim 40 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

44. The spinal fusion implant of claim 40 in which said implant has means for closing said access opening.

15 45. The spinal fusion implant of claim 26 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

20 46. The spinal fusion implant of claim 26 in which at least a portion of said outer surface comprises wells having at least partial walls.

25 47. The spinal fusion implant of claim 26 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

30 48. The spinal fusion implant of claim 26 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

49. The spinal fusion implant of claim 48 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

50. An interbody spinal fusion implant, comprising:

5 a body having a substantially cylindrical configuration, an insertion end, a trailing end and an outer surface; and

10 an external thread for engaging said implant to adjacent vertebrae of the spine, the locus of said external thread forming a substantially cylindrical configuration, said implant being made of a material appropriate for human implantation.

51. The spinal fusion implant of claim 50 in which said implant comprises a bone ingrowth material.

15 52. The spinal fusion implant of claim 50 in which said implant comprises a fusion promoting material.

53. The spinal fusion implant of claim 50 in which said implant is at least in part bioabsorbable

20 54. The spinal fusion implant of claim 50 having a plurality of openings capable retaining fusion promoting material.

25 55. The spinal fusion implant of claim 50 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform for at least a portion of said implant.

30 56. The spinal fusion implant of claim 50 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along at least a portion of said implant.

57. The spinal fusion implant of claim 50 in which said external thread has a thread height measured from said body which is variable along at least a portion of said implant.

5 58. The spinal fusion implant of claim 50 in which said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

59. The spinal fusion implant of claim 51 in which
10 said outer surface is porous at least in part.

60. The spinal fusion implant of claim 51 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

61. The spinal fusion implant of claim 60 in which
15 said internal chamber is capable of containing fusion promoting material.

62. The spinal fusion implant of claim 60 in which said implant comprises a wall surrounding said internal chamber.

20 63. The spinal fusion implant of claim 60 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

64. The spinal fusion implant of claim 60 in which said implant has means for closing said access opening.

25 65. The spinal fusion implant of claim 51 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

66. The spinal fusion implant of claim 51 in which at
30 least a portion of said outer surface comprises wells having at least partial walls.

67. The spinal fusion implant of claim 51 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

68. The spinal fusion implant of claim 51 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

69. The spinal fusion implant of claim 68 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

70. A frusto-conical interbody spinal fusion implant, comprising:

a body having a substantially frusto-conical configuration, an insertion end, a trailing end and an outer surface; and

an external thread for engaging said implant to adjacent vertebrae of the spine, said implant being made of a material appropriate for human implantation.

71. The implant of claim 70 in which said the outer locus of said external thread forms a substantially cylindrical configuration.

72. The spinal fusion implant of claim 70 in which said insertion end is larger than said trailing end.

73. The spinal fusion implant of claim 72 in which said insertion end comprises a tapered leading portion.

74. The spinal fusion implant of claim 70 in which said trailing end is larger than said insertion end.

75. The spinal fusion implant of claim 70 in which said implant comprises a bone ingrowth material.

76. The spinal fusion implant of claim 70 in which said implant comprises a fusion promoting material.

5 77. The spinal fusion implant of claim 70 in which said implant is at least in part bioabsorbable.

78. The spinal fusion implant of claim 70 having a plurality of openings capable retaining fusion promoting material.

10 79. The spinal fusion implant of claim 70 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being substantially uniform throughout the length of said implant.

15 80. The spinal fusion implant of claim 70 in which said external thread has a thread radius measured from the longitudinal central axis of said implant, said thread radius being variable along the length of said implant.

20 81. The spinal fusion implant of claim 70 in which said external thread has a thread height measured from said body which is variable along the length of said implant.

25 82. The spinal fusion implant of claim 70 in which said external thread has a thread height measured from said body which is substantially constant along the length of said implant.

83. The spinal fusion implant of claim 70 in which said outer surface is porous at least in part.

30 84. The spinal fusion implant of claim 70 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

85. The spinal fusion implant of claim 84 in which said internal chamber is capable of containing fusion promoting material.

5 86. The spinal fusion implant of claim 84 in which said implant comprises a wall surrounding said internal chamber.

87. The spinal fusion implant of claim 84 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

10 88. The spinal fusion implant of claim 84 in which said implant has means for closing said access opening.

89. The spinal fusion implant of claim 70 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of
15 said implant.

90. The spinal fusion implant of claim 70 in which at least a portion of said outer surface comprises wells having at least partial walls.

91. The spinal fusion implant of claim 70 in which
20 said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said
25 first and second implants.

92. The spinal fusion implant of claim 70 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

93. The spinal fusion implant of claim 92 in which
30 said external thread has a thread height measured from said body which is greatest at said truncated side.

94. The spinal fusion implant of claim 1 in which said implant has an upper and lower portion for engaging the bone of the adjacent vertebrae, said upper and lower surfaces comprising a plurality of macroscopic openings.

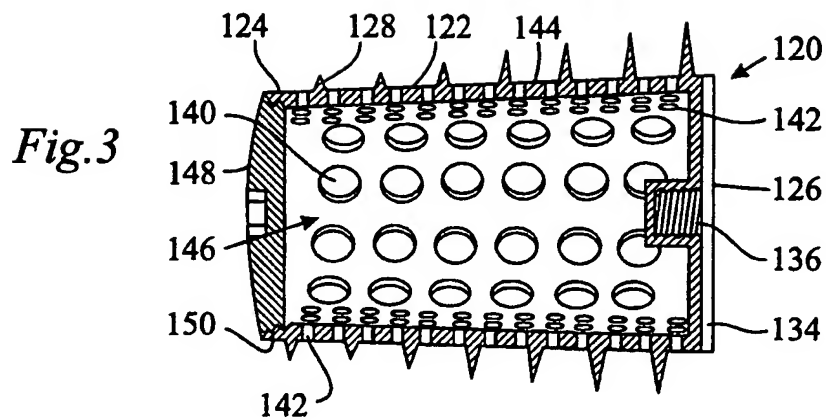
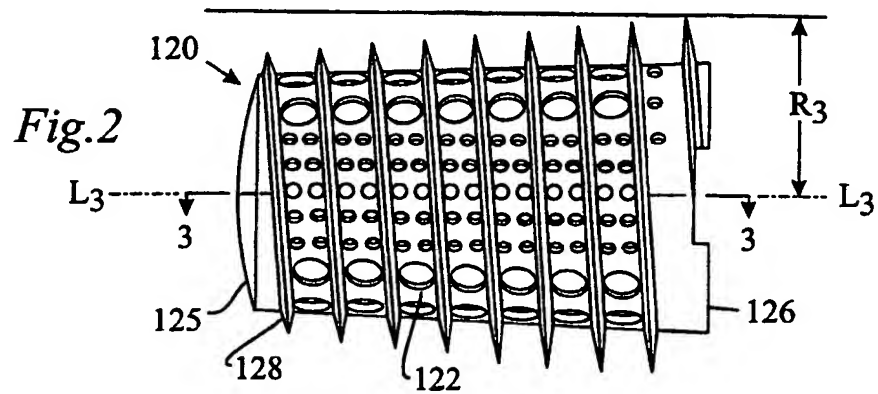
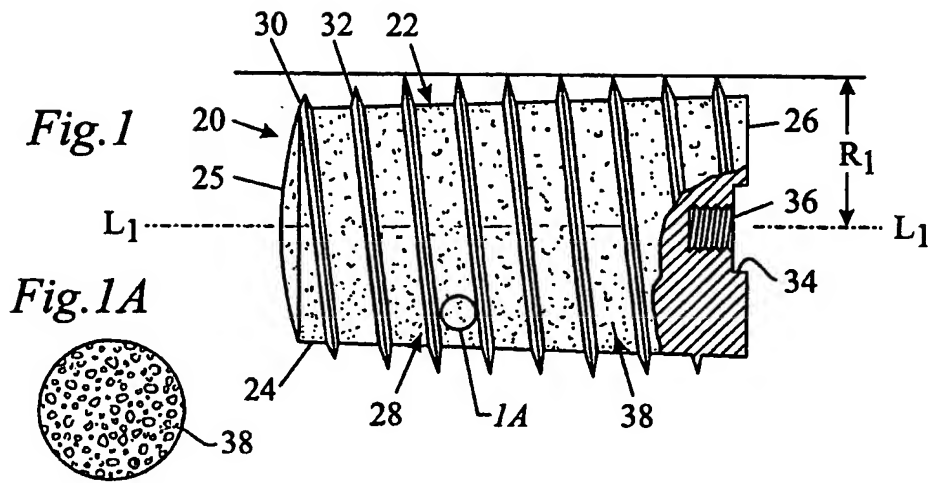
5 95. The spinal fusion implant of claim 26 in which said implant has an upper and lower portion for engaging the bone of the adjacent vertebrae, said upper and lower surfaces comprising a plurality of macroscopic openings.

10 96. The spinal fusion implant of claim 50 in which said implant has an upper and lower portion for engaging the bone of the adjacent vertebrae, said upper and lower surfaces comprising a plurality of macroscopic openings.

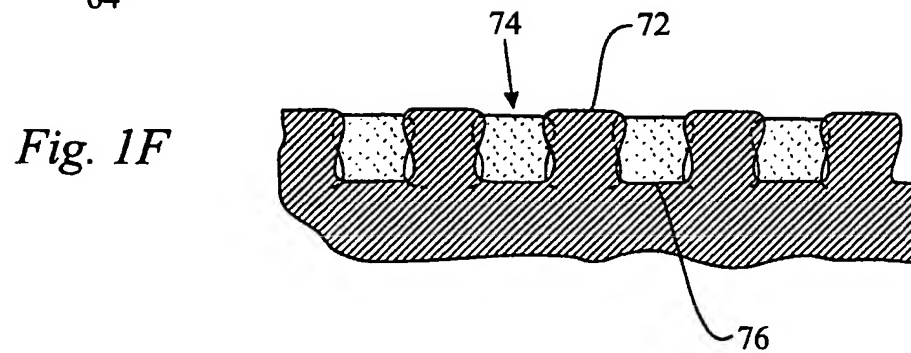
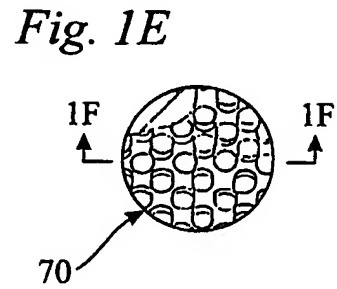
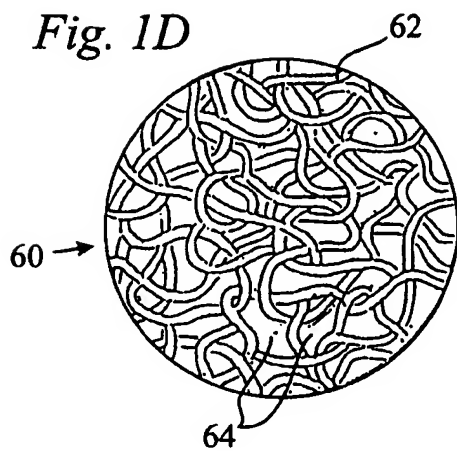
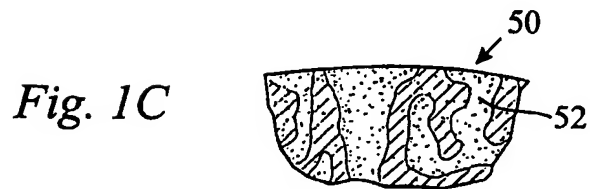
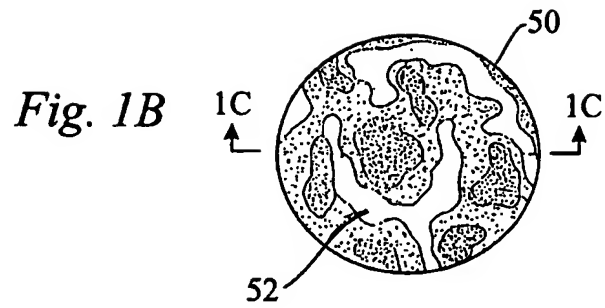
15 97. The spinal fusion implant of claim 70 in which said implant has an upper and lower portion for engaging the bone of the adjacent vertebrae, said upper and lower surfaces comprising a plurality of macroscopic openings.

98. The spinal fusion implant of claim 24 in which said external thread is continuous over at least a portion of said truncated side.

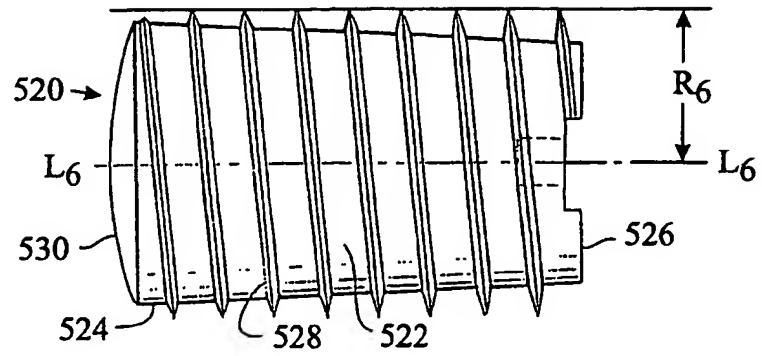
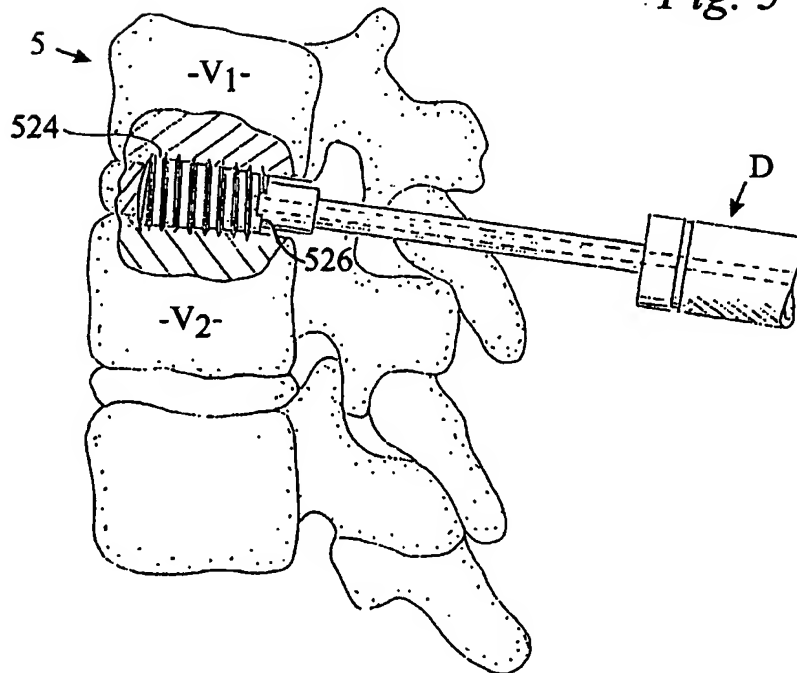
1 / 4



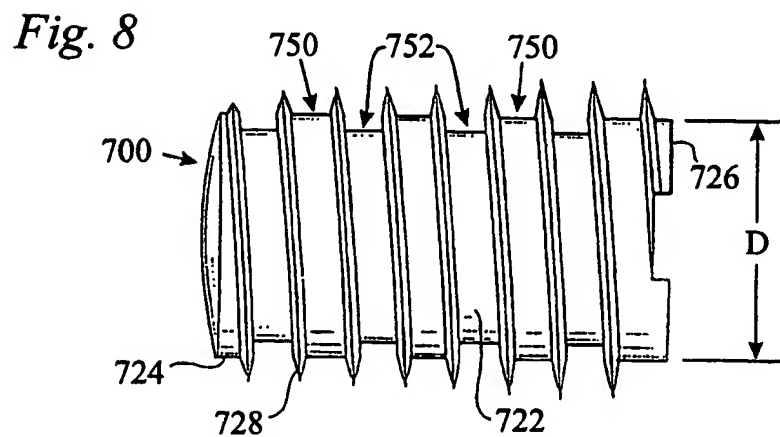
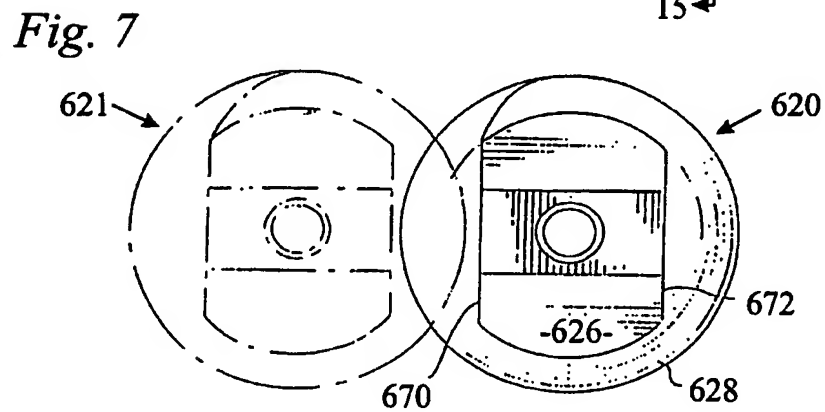
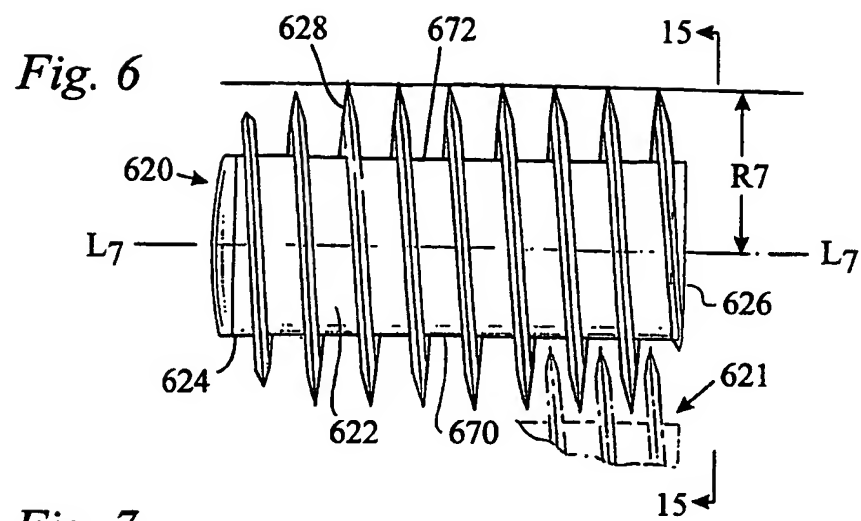
2 / 4



3 / 4

Fig. 4*Fig. 5*

4 / 4



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/08618

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 5/04

US CL :606/61; 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/60, 61, 72-78; 623/16-18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,349,921 A (KUNTZ) 21 September 1982, entire document.	1, 2, 4, 26, 27, 29, 70, 72, 73 ----- 3, 5, 8, 9, 11, 13, 22, 28-46, 53, 56-58, 71, 74, 75-90, 94-97

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

27 OCTOBER 1996

Date of mailing of the international search report

06 NOV 1996

 Name and mailing address of the ISA/US
 Commissioner of Patents and Trademarks
 Box PCT
 Washington, D.C. 20231

Authorized officer

MICHAEL A. BROWN

Facsimile No. (703) 305-3590

Telephone No. (703) 308-2682

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/08618

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,961,740 A (RAY et al) 09 October 1990, entire document	6, 7, 9, 11, 14, 15-22, 31, 32, 34, 35, 39-46, 50-52, 54, 55, 59-66, 75, 76, 78, 79, 82-90, 94-97
Y	US 4,904,260 A (RAY et al) 27 February 1990, entire document.	8, 33, 53, 77